



United States
Department of
Agriculture

January 4, 2002

Marketing and
Regulatory
Programs

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-02

Animal and Plant
Health Inspection
Service

Subject: Change in Finished Label Submission Requirement

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

Center for Veterinary
Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

I. PURPOSE

The purpose of this notice is to inform interested parties of a reduction in the number of copies of finished labels for biological products required to be submitted to the Center for Veterinary Biologics (CVB) for approval and filing.

II. POLICY

Labels used with biological products prepared at licensed establishments or imported for distribution and sale must be submitted to the CVB for approval prior to use. The number of copies of labels required to be submitted is specified in 9 CFR 112.5 (d). As part of ongoing efforts to streamline critical processes, the CVB has merged portions of their filing systems, reducing the number of copies of labels necessary for filing purposes.

Effective immediately, establishments need provide only two copies of finished labeling materials submitted in accordance with 9 CFR 112.5 (d)(1)(iii) and (iv), rather than three as currently stated. The number of label sketches, per 9 CFR 112.5 (d)(1)(i) and (ii), is not changed; two copies of label sketches should continue to be provided.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



APHIS - Protecting American Agriculture
An Equal Opportunity Employer